IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent application of:

Applicant(s):	Vilsmeier et al.
Serial No.:	10/634,133
Filed:	August 4, 2003
Title:	PATIENT POSITIONING SYSTEM FOR RADIOTHERAPY/RADIOSURGERY BASED ON MAGNETICALLY TRACKING AN IMPLANT
Examiner:	Nasir Shahrestani
Art Unit:	3737
Docket No.	SCHWP0185USA

APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The undersigned submits this brief for the Board's consideration of the appeal of the Examiner's decision, mailed February 17, 2010, finally rejecting claims 1-20 of the above-identified application.

The fee for filing an appeal brief was previously submitted in connection with the appeal brief filed on December 22, 2008, and therefore no additional fee is believed to be due. In the event an additional fee or further extension of time is necessary, the Commissioner is authorized to charge any additional fee which may be required, and further to consider this a petition for an extension of time to make the filing of this brief timely, to Deposit Account No. 18-0988 under Docket No. SCHWP0185USA.

I. Real Party in Interest

The real party in interest in the present appeal is BrainLAB AG, the assignee of the present application.

II. Related Appeals and Interferences

Neither appellant nor appellant's legal representative are aware of any appeals or interferences which will directly affect, which will be directly affected by, or which will have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

Claims 1-20 are pending in the application and stand finally rejected. The claims on appeal are claims 1-20, and a correct copy of these claims is reproduced in the Claims Appendix.

IV. Status of Amendments

No claim amendments were filed subsequent to the issuance of the Final Office Action of February 17, 2010 from which this appeal is taken.

V. Summary of Claimed Subject Matter[1]

The following is a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which refers to the specification by page and line number in brackets, and to the drawings by reference characters.

1. A method for detecting a target volume in radiotherapy or radiosurgery, said method comprising:

positionally referencing at least one implant in the vicinity of the target volume **10** [p. 3 lines 27-29];

inductively stimulating the at least one implant **20** [p. 3 lines 28-29];

detecting emission from the at least one inductively stimulated implant **30** [p.3 line 30 – p. 4 line 1];

determining a position of the at least one implant based on the detected emission **40** [p. 4 lines 1-2]; and

determining the current position of the target volume based on the determined position of the at least one implant **50** [p. 4 lines 2-4].

19. A method for recording diagnostic, two dimensional or three dimensional image data sets in accordance with breathing [p. 5 line 28 – p. 6 line 10], said method comprising:

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[1] This summary is presented in compliance with the requirements of 37 C.F.R. §41.37(c)(1)(v), mandating a concise explanation involved in the appeal. Nothing contained in this summary is intended to change the specific language of the claims described, nor is the language in the summary to be construed so as to limit the scope of the claims in any way.

introducing at least one implant into a patient in the vicinity of the target volume **10** [p. 3 lines 27-29];

inductively stimulating the at least one implant **20** [p. 3 lines 28-29];

detecting emission from the at least one inductively stimulated implant **30** [p. 3 line 30 – p.4 line 1];

determining a position of the at least one implant based on the detected emission **40** [p. 4 lines 1-2]; and

recording image data based on the position of the at least one implant [p. 6 lines 7-10].

VI. Grounds of Objection/Rejection to Be Reviewed on Appeal

A. Claims 1-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,405,072 (referred to herein as *Cosman*) in view of U.S. 6,733,485 (referred to herein as *Whitehurst*).

VII. Argument

The rejections advanced by the Examiner are improper and should be reversed for at least the following reasons.

Background

In radiotherapy and radiosurgery, major progress has been achieved in dosage planning. The aim of dosage planning is to use higher radiation doses, and these higher does are applied to a target volume (e.g., a tumor) as precisely as possible so as to not damage the surrounding regions. Although dosage planning has been shown to

be relatively successful, the use of higher doses can be hindered if the section of the body to be treated cannot be precisely located. For example, due to the patient's breathing the target volume may shift up to 2 cm. If such movement is not taken into account, then treatment is not optimal.

Thus, in order to ensure optimal treatment, it is necessary to know the exact position of the target volume within the patient at any time during the treatment (including position shifts due to breathing movement). If the position is precisely known, then it is possible to activate the therapy device only when the target volume is within a range of tolerance of the target area of the therapy device or, if it can be set in the design of the machine in question, to slave the target area of the therapy machine to the movement of the target volume.

A related problem arises when recording diagnostic images on which the treatments are based. If the target volume of the patient moves while the image data is being recorded, then artifacts result in the images and the geometrical proportions of the interior of the patient are distorted in the image data. Consequently, the target volume within the patient may not be detected in its true size, but instead may be shown too large or too small.

In accordance with one aspect of the present invention, a method for detecting a target volume in radiotherapy or radiosurgery is provided. According to the method, at least one implant in the vicinity of the target volume is positionally referenced. The at least one implant is inductively stimulated, and an emission from the at least one inductively stimulated implant then is detected. A position of the at least one implant is

determined based on the detected emission, and then a current position of the target volume is determined based on the determined position of the at least one implant.

In accordance with another aspect of the invention, a method for recording diagnostic, two dimensional or three dimensional image data sets in accordance with breathing is provided. The method includes introducing at least one implant into the patient in the vicinity of the target volume and inductively stimulating the at least one implant. Emission from the at least one inductively stimulated implant is detected and a position of the at least one implant is determined based on the detected emission. Image data then is recorded based on the position of the at least one implant.

A. Rejection of Claims 1-12 and 18-20 under 35 U.S.C. § 103(a)

Claims 1-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Cosman* in view of *Whitehurst*

Claim 1

Claim 1 recites a method for detecting a target volume in radiotherapy or radiosurgery. The method includes positionally referencing at least one implant in the vicinity of the target volume, inductively stimulating the at least one implant, and detecting emission from the at least one inductively stimulated implant. Based on the detected emission, a position of the at least one implant is determined, and the determined position of the at least one implant is used to determine the current position of the target volume. The Examiner's comments in support of the rejection of claim 1 are set forth below.

"Cosman teaches a method for detecting a target volume (title) in radiotherapy or radiosurgery (fig. 2), the method comprising: referencing a marker in the vicinity of the target volume (col. 3 lines 29-36) in order to provide parameters indicative of a target volume.

Cosman does not teaches the use of markers (ex-vivo) and the use of internally placed implants. Furthermore, Cosman does not teach the inductive stimulation of such implants to provide data indicative of a target volume.

Whitehurst et al. teach referencing at least one implant in the vicinity of the target volume (fig. 6) and inductively stimulating the at least one implant (inductive coil 146).

It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Cosman and to have included implant localization and stimulation as taught by Whitehurst in order to provide a clear representation of a target volume while stimulating implanted elements that would provide a further indication of a location as well as the potential for therapeutic applications."[2]

1. A Prima Facie Case of Obviousness has not been Established

The Examiner admits that *Cosman* fails to teach the use of internally placed implants and inductively stimulating at least one implant to provide data indicative of a target volume. The Examiner, however, contends that *Whitehurst* teaches referencing an implant in the vicinity of a target volume and inductively stimulating the at least one implant. Clearly absent from the Examiner's statement of the rejection is any comment with respect to how either *Cosman* or *Whitehurst* teach the claimed features of ***determining a position of the at least one implant based on the detected emission***, and ***determining a current position of the target volume based on the determined position of the at least one implant***. Therefore, the Examiner has not shown each and every claimed feature in the cited art and, thus, has not established a

[2] Pages 2-3 of the final Office Action

prima facie case of obviousness. For at least this reason, reversal of the rejection of claim 1 is respectfully requested.

2. Determining a Position of the Implant Based on a Detected Emission

Claim 1 sets forth that a position of the at least one implant is determined ***based on a detected emission from the implant***. As noted above, the Examiner has not addressed this feature. This is because such feature is not present in *Whitehurst* or in *Cosman*.

Whitehurst discloses an implantable stimulator that includes electrodes for delivering electrical stimulation to surrounding tissue and/or a pump for delivering a drug to surrounding tissue. The device includes a power/data circuit for receiving power and/or data from outside the body by inductive, radio frequency or other electromagnetic coupling. In use, the device provides electrical stimulation and/or administration of a drug based on predetermined parameters, which may be stored in the implant.[3]

Admittedly, *Whitehurst* discloses that the stimulator may be "inductively stimulated" for purposes of powering the device and to communicate data to/from the stimulator. However, *Whitehurst* is silent with respect to ***determining a position of the stimulator based on detected emissions from the stimulator***.

Moreover, *Whitehurst* is not concerned with detecting a position of the stimulator, let alone basing its position on emissions from the stimulator. More specifically, the purpose of *Whitehurst's* stimulator is to provide electrical stimulation to tissue of the

[3] See, e.g., Abstract, column 11, lines 30-36, column 15, lines 26-40,

patient.[4] Such stimulation is provided via electrodes that are in contact with the tissue. Should the tissue move (e.g., due to breathing) the electrodes and stimulator also move with the tissue (i.e., once implanted, there presumably is little or no relative movement between the electrodes and the tissue). Thus, once the stimulator is implanted in the patient, movement of the tissue and stimulator has no effect on the system of *Whitehurst*.

Accordingly, there is no reasonable basis for one having ordinary skill in the art to modify the system of *Whitehurst* to use data emitted by the stimulator to determine a position of the stimulator, as such position information simply is not relevant in the operation of *Whitehurst's* system.

Regarding *Cosman*, as admitted by the Examiner this reference does not teach inductive stimulation of implants to provide data indicative of a target volume. Thus, *Cosman* does not make up for the deficiencies of *Whitehurst*.

Accordingly the combination of *Cosman* and *Whitehurst* simply does not teach or fairly suggest a method for detecting a target volume in radiotherapy or radiosurgery, the method including, *inter alia*, inductively stimulating the at least one implant, detecting emission from the at least one inductively stimulated implant, and determining a position of the at least one implant based on the detected emission as claimed.

For at least the above reasons, reversal of the rejection of claim 1 is respectfully requested.

[4] See, e.g., Abstract

Claim 2

Claim 2 depends from claim 1 and thus the above comments with respect to claim 1 are also applicable to claim 2. Claim 2 further recites introducing the at least one implant into the patient in the vicinity of the target volume, detecting the position of the at least one introduced implant using an imaging system before radiation treatment, and referencing the at least one introduced implant relative to inner organs or other body structures. The Examiner's comments in support of the rejection of claim 2 are set forth below.

> "Cosman further teaches introducing the at least one implant into the patient in the vicinity of the target volume (column **11** lines 4-5); detecting the position of the implant using an imaging system (column 1 lines 65-67); and referencing an implant relative to inner organs and anatomical structures (column 3 lines 29-32)."[5]

In the context of claim 2, "the at least one implant" is the implant that is inductively stimulated (see claim 1). As noted above, the Examiner admits that *Cosman* does not teach inductive stimulation of implants. Thus, reliance on *Cosman* as set forth above for teaching introduction into a patient of an implant that is to be inductively stimulated is clearly unsupported.

Moreover, the cited passages of *Cosman*, which are reproduced below, fail to disclose the claimed features.

> "Three-dimensional scan data has been employed to relate positions in a patient's anatomy to other structures so as to provide a composite graphics display."[6]

> "Basically, scan data is stored to specify the location of a target in a patient's body, generally defined in three-dimensional scan space (as slice data) with respect to references."[7]

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[5] Page 3 , fourth paragraph of the final Office Action
[6] Column 1, lines 65-67 of *Cosman*
[7] Column 3, lines 29-32 of *Cosman*

> "Thus, diagnostic X-rays from machines 80 and 81 or high energy X-rays for portal imaging can be used to visualize internal anatomy such as bones and/or radiopaque index markers placed on the skin or implanted in bones or tissue within the patient prior to treatment."[8]

As can be seen in the above cited passages, the only objects that may reasonably be regarded as an implant are the radiopaque markers (they are the only object in the cited passages that may actually be implanted into the patient). As is well known by one having ordinary skill in the art, radiopaque markers are used in medical imaging, such as x-ray imaging. Such markers image by blocking, for example, x-ray radiation. One having ordinary skill in the art would not be inclined to "inductively stimulate" a radiopaque marker. Further, there is no reasonable basis to conclude one having ordinary skill in the art would attempt to detect an emission from an inductively stimulated radiopaque marker, or determine a position of the inductively stimulated radiopaque marker based on the detected emission. Moreover, *Cosman* does not teach how one may detect a position of a radiopaque marker based on an emission from an inductively stimulated radiopaque marker.

For at least the above reasons, reversal of the rejection of claim 2 is respectfully requested.

Claim 3

Claim 3 depends from claim 2 and thus the above comments with respect to claim 2 are also applicable to claim 3. Claim 3 further recites after detecting the position of the at least one introduced implant, moving the patient to a therapy device; at the

[8] Column 11, lines 4-5 of *Cosman*

therapy device, generating a dynamic electromagnetic field in the vicinity of but outside the patient, wherein the at least one implant inductively absorbs energy via the electromagnetic field and the at least one implant at least partially re-emits the absorbed energy in the form of a second electromagnetic signal; detecting the second electromagnetic signal outside the patient; and determining the position of the at least one implant relative to measuring points at which the second electromagnetic signal is detected, the position of said measuring points relative to the therapy device being known. The Examiner's comments in support of the rejection of claim 3 are set forth below.

> "Cosman further teaches moving the patient to a therapy device after detecting the implant (column 3 lines 42-46; column 7 lines 1-6); and generating an electromagnetic field in the vicinity of but outside the patient (column 20 lines 28-31), wherein the implant inherently inductively absorbs energy and at least partially re-emits the absorbed energy being in the form of a second EM signal; and detecting said second EM signal outside the patient (column 4 lines 62-67); and determining the position of said implant relative to measuring points at which said second EM signal is detected and position of said measuring points relative to the therapy device being inherently known by user (fig. 2; fig. 10)."[9]

The cited portions of *Cosman* are also reproduced below.

> "Note that both the machine L and a patient-supporting couch F are moveable to accomplish and maintain desired positional relationships between the beam B and the patient P as described in greater detail below."[10]

> "After determining the position of desired treatment target in the patient P using the coordinate space of the camera system C and also determining the relative position and distance of that target from the isocenter point 7, also in camera space, the couch F is moved to access the desired target with the isocenter point 7."[11]

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[9] Page 3, last paragraph of the final Office Action
[10] Column 3, lines 43-46 of *Cosman*
[11] Column 7, lines 1-6 of *Cosman*

> "Typically, X-ray fields or electromagnetic fields emanating from apparatus 191 for CT or MRI scanning are used to perform volumetric or tomographic scanning on the patient."[12]
>
> "Regarding the camera system C, the individual optical cameras 17, 18 and 19 essentially "look" at the position and orientation of the patient P, that is, viewing the volume containing the patient P and the apparatus as explained above. The markers 20, 21, 23 and 24 can be "seen" by the cameras to track marker positions relative to the isocenter point 7 and the beam B."[13]

It is respectfully submitted that the "generating a dynamic electromagnetic field in the vicinity of but outside the patient, wherein the at least one implant inductively absorbs energy via the electromagnetic field and the at least one implant at least partially re emits the absorbed energy" limitation of the claim is wholly missing from *Cosman*. Specifically, column 3, lines 42-46 of *Cosman* pertain to positioning an x-ray beam B, column 7, lines 1-6 pertain to directing the beam B to the target region, and column 4, lines 62-68 refer to using a camera system to look at the position and orientations of the patient (referred to as the volume containing the patient). None of these portions even refer to generating a dynamic electric field as claimed. Regarding column 20 lines 28-31, this passage mentions an electromagnetic field, but this is in the context of use for CT or MRI scanning. No teaching is found of an implant absorbing energy via the electromagnetic field and the at least one implant at least partially remitting the absorbed energy as claimed.

[12] Column 20, lines 28-31 of *Cosman*
[13] Column 2, lines 62-67 of *Cosman*

Regarding Figs. 2 and 10 (reproduced below), there is no indication in these figures of generating a dynamic electromagnetic field as claimed.

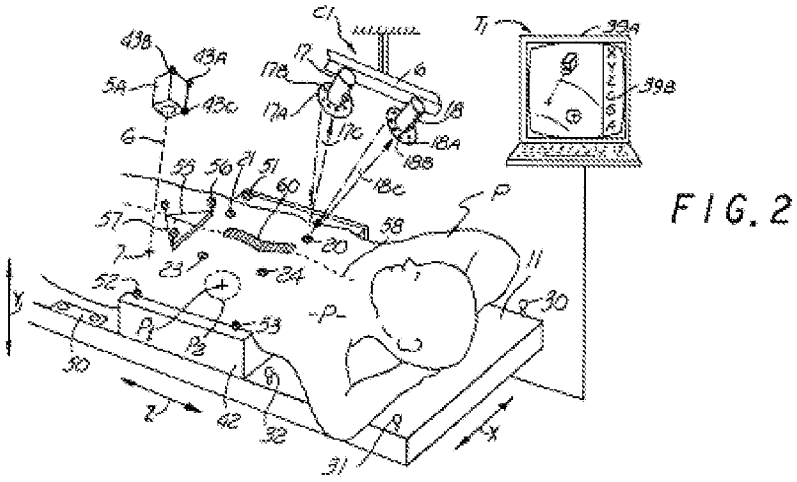

FIG. 2

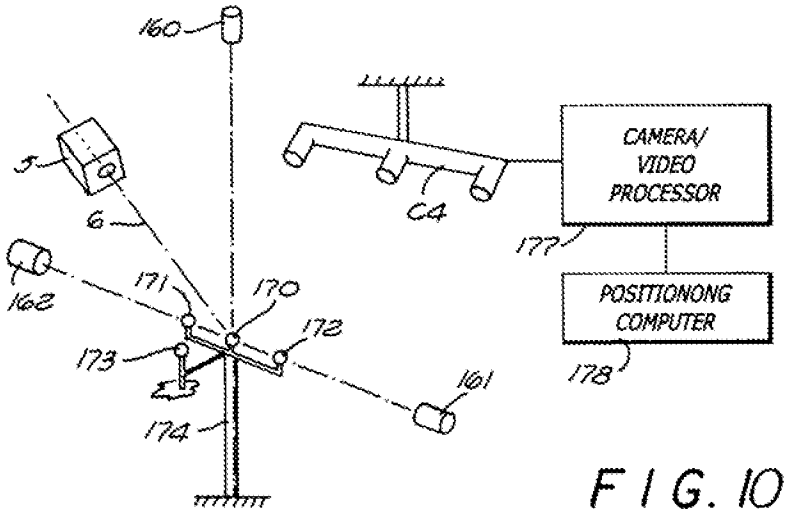

FIG. 10

For at least the above reasons, reversal of the rejection of claim 3 is respectfully requested.

Claim 4

Claim 4 depends from claim 3 and thus the above comments with respect to claim 3 are also applicable to claim 4. Claim 4 further recites determining the current position of the target volume based on the determined position of the at least one implant and knowledge of the position of the patient's inner organs relative to the at least one implant. The Examiner does not appear to specifically address the features of claim 4 in the final Office Action. Thus, the Examiner has not established a *prima facie* case of obviousness for claim 4.

For at least the above reasons, reversal of the rejection of claim 4 is respectfully requested.

Claim 7

Claim 7 depends from claim 4 and thus the above discussion with respect to claim 4 is also applicable to claim 7. Claim 7 further recites continuously detecting the position of the at least one implant; and based on the continuously detected position, determining a shift in the position of the target volume caused by breathing. The Examiner's comments in support of the rejection of claim 7 are set forth below.

> "Cosman further teaches continuously detecting the position of the implant and determining a shift in the position of the target volume caused by breathing based on the detected position (dashed lines 155; column 16 lines 60-67)."[14]

The cited portion of *Cosman* also is reproduced below.

> "The dashed line 155 represents the boundary of the external contour of the body from the projected reconstructed view derived from the prior image scan data along an axis parallel to axis 143. Dashed lines 155 then represent a computer generated contour of the external projection of the

[14] Page 4, third paragraph of the final Office Action

> patient's body to simulate the actual video boundary line 154. The non-coincidence of dashed line 155 compared to solid line 154 in FIG. 9A represents the degree of translational shift or body movement needed to bring the lines into registration."[15]

The dashed line 155 referred to by the Examiner actually represents a boundary of the external contour of the body, and not a continuously detected position. Moreover, absent from the cited portion of *Cosman* is any teaching or suggestion of continuously detecting the position of the at least one implant or the determination of a shift in the position of the target volume caused by breathing. Thus, the Examiner has not established a *prima facie* case of obviousness for claim 7.

For at least the above reasons, reversal of the rejection of claim 7 is respectfully requested.

Clam 8

Claim 8 depends from claim 4 and thus the above comments with respect to claim 4 are also applicable to claim 8. Claim 8 further recites based on the current position of the at least one implant, activating the therapy device only when the position of the target volume is within a predetermined range about a current target point of the therapy device. The Examiner's comments in support of the rejection of claim 8 are set forth below.

> "Cosman further teaches activating the therapy device only when the position of the target volume is within a predetermined range bout a current target point of the therapy device (column 21 lines 6-28)."[16]

The cited portion of *Cosman* is also reproduced below.

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[15] Column 16, lines 60-67 of *Cosman*
[16] Page 4, first paragraph of the final Office Action

> "As one illustrated example, a patient may have been scanned by CT or MR to determine the position of a tumor in his body or his cranium. Based on that information and a treatment planning processor such as 36, surgery or other intervention may be planned. It may be desired to determine the degree, for example, of the tumor as the resection is taking place. In this situation, a CT, MR, PET, or other scanner may be placed in or near the operating room, and during the surgery a scan of the patient is required in or around the region where the tumor was identified by the previous imaging, and/or around the region where the surgeon is resecting. In that case, use of the optical tracking system as in FIG. 11 in conjunction with knowledge of a reference point(s) 192 in such an interoperative scanner would enable the clinician to move the predetermined target region 44 or interoperatively determined target position 44 to a region near the reference point 187 so that the interoperative CT, MR, etc. scans will give meaningful information for its update of surgery. The use of controller system 178 coupled to couch top 11 and the coupling to other controls of the image scanner viz. couch movement/readout would follow along the discussion above in connection with the previous figures."[17]

Clearly absent for the cited portion of *Cosman* is any teaching of activating the therapy device only when the position of the target volume is within a predetermined range about a current target point of the therapy device. Thus, the Examiner has not established a prima facie case of obviousness for claim 8.

For at least the above reasons, reversal of the rejection of claim 8 is respectfully requested.

Claim 9

Claim 9 depends from claim 8 and thus the above comments with respect to claim 8 are also applicable to claim 9. Claim 9 further recites wherein knowledge of the current position of the target volume within the patient is used to adjust the therapy device such that the target point of the therapy device follows the shift of the target volume. The Examiner does not appear to specifically address the features of claim 9 in

[17] Column 21, lines 6-28 of *Cosman*

the final Office Action. Thus, the Examiner has not established a *prima facie* case of obviousness for claim 9.

For at least the above reasons, reversal of the rejection of claim 9 is respectfully requested.

Claim 10

Claim 10 depends from claim 3 and thus the above comments with respect to claim 3 are also applicable to claim 10. Claim 10 further recites wherein the measuring points are situated on a rotating portion of a linear accelerator. The Examiner's comments in support of the rejection of claim 10 are set forth below.

> "Cosman further teaches wherein the measuring points are situated on a rotating portion of a linear accelerator (fig. **11** elements 40A, 40B, 40C)."[18]

The "measuring points" of the claim refer to "the position of the points at which the emitted electromagnetic radiation is detected" (see claim 3). These "measuring points" are the locations of the magnetic tracking system's receivers. The Examiner incorrectly equates the ***optical*** index markers 40A, 40B, and 40C of figure 11 of *Cosman* to the claimed measuring points (or locations of the receivers). Such optical index markers are not measuring points at which emitted electromagnetic radiation is detected.

For at least the above reasons, reversal of the rejection of claim 10 is respectfully requested.

[18] Page 4, 4th paragraph of the final Office Action

Claim 11

Claim 11 depends from claim 3 and thus the above comments with respect to claim 3 are applicable to claim 11. Claim 11 further recites wherein the measuring points are integrated into a treatment couch of the therapy device. The Examiner's comments in support of the rejection of claim 11 are set forth below.

> "Cosman further teaches wherein the measuring points are integrated into a treatment couch of the therapy device (fig. **11** elements 32, 30, 31)."[19]

The "measuring points" of the claim refer to "the position of the points at which the emitted electromagnetic radiation is detected" (see claim 3). These "measuring points" are the locations of the magnetic tracking system's receivers. The Examiner incorrectly equates the ***optical*** index markers 30, 31, and 32 of figure 11 of *Cosman* to the claimed measuring points (or locations of the receivers). Such optical index markers are not measuring points at which emitted electromagnetic radiation is detected.

For at least the above reasons, reversal of the rejection of claim 11 is respectfully requested.

Claim 12

Claim 12 depends from claim 3 and thus the above comments with respect to claim 3 are also applicable to claim 12. Claim 12 further sets forth wherein one or more measuring points are attached to a solid, mobile structure, the position of which is tracked relative to the therapy device by means of a real time tracking system. The Examiner's comments in support of the rejection of claim 12 are set forth below.

> "Cosman further teaches wherein one or more measuring points are attached to a solid mobile structure as mentioned above, which position

[19] Page 4, 5th paragraph of the final Office Action

relative to the therapy device is tracked three-dimensionally by means of a real-time tracking system (column 7 lines 25-41; column 8 lines 31-41)."[20]

The cited portion of *Cosman* is also reproduced below.

> "In a dynamic mode of the system, corrections may be provided for patient movement during treatment along with continual confirmation of the patient's body position relative to the LINAC machine. If there is respiratory body movement of the patient P, as would typically occur in the torso region, the tidal movement can be observed by the camera system C tracking the index markers 20, 21, 23 and 24. Synchronizing the radiation from the LINAC machine L can assure that the anatomical target is impacted by the beam 6 even though the patient's internal organs are moving. This too can be controlled by the controller 38 with feedback to the optical tracking processor 34 through the comparator 37. Consequently, the comparator 37 enables streamlining certain complex procedures and even routine procedures, as compared to standard current radiotherapy steps relying primarily on laser lights associated with a radiation machine and tatoo markings on the patient."[21]

> "Also as noted, the terminal unit 39A incorporates the capability to control and display positional data. Specifically, as indicated, a display panel 39B indicates, in X, Y and Z coordinates, the position of the isocenter relative to a target in real time, e.g. currently, as well as the angles C, G and A (corresponding to LINAC angles 12A for couch rotations, 2A for gantry rotations, and A for collimator rotations as indicated by the arrows in FIG. 1) regarding the beam 6 in the coordinate system of the patient's anatomy in scan data space as rendered from the treatment planning computer embodied in the unit 39."[22]

The "measuring points" of the claim refer to "the position of the points at which the emitted electromagnetic radiation is detected" (see claim 3). These "measuring points" are the locations of the magnetic tracking system's receivers, and are attached to a solid, mobile structure the position of which is tracked relative to the therapy device by means of a real time tracking system. The only items tracked in the cited portion of *Cosman* are ***optical*** markers (via camera system). The cited portions of *Cosman* do

[20] Page 4, 6th paragraph of the final Office Action
[21] Column 7, lines 25-41 of *Cosman*
[22] Column 8, lines 31-41 of *Cosman*

not disclose that measuring points for electromagnetic radiation are tracked three dimensionally by means of a real time tracking system.

For at least the above reasons, reversal of the rejection of claim 12 is respectfully requested.

Claim 13

Claim 13 indirectly depends from claim 2 and thus the above comments with respect to claim 2 are also applicable to claim 13. Claim 13 further recites wherein the at least one implant includes one or more coils. The Examiner does not appear to specifically address the features of claim 13 in the final Office Action. Thus, the Examiner has not established a *prima facie* case of obviousness for claim 13.

For at least the above reasons, reversal of the rejection of claim 13 is respectfully requested.

Claim 14

Claim 14 indirectly depends from claim 2 and thus the above comments with respect to claim 2 are also applicable to claim 14. Claim 14 further recites wherein the at least one implant includes a number of coils whose axes are not parallel to each other. The Examiner does not appear to specifically address the features of claim 14 in the final Office Action. Thus, the Examiner has not established a *prima facie* case of obviousness for claim 14.

For at least the above reasons, reversal of the rejection of claim 14 is respectfully requested.

Claim 15

Claim 15 indirectly depends from claim 2 and thus the above comments with respect to claim 2 are also applicable to claim 15. Claim 15 further recites wherein the coils in the at least one implant are connected to different oscillating circuits having different resonance frequencies. The Examiner does not appear to specifically address the features of claim 15 in the final Office Action. Thus, the Examiner has not established a *prima facie* case of obviousness for claim 15.

For at least the above reasons, reversal of the rejection of claim 15 is respectfully requested.

Claim 16

Claim 16 depends from claim 1 and thus the above comments with respect to claim 1 are also applicable to claim 16. Claim 16 further recites while the at least one implant is tracked, a patient is situated in a space or region of a space in which there are as few interference fields as possible and in which there are as few metallic parts as possible; the position of the at least one implant relative to measuring points is determined; the measuring points are fixedly connected to the patient or to a couch on which the patient is lying; the measuring points are fitted with a reference means which allows the position of the measuring points to be determined using an independent, three-dimensional tracking system; after electromagnetic measuring, the patient is moved to a therapy device in such a way that the spatial relationship between the

patient and the measuring points is not changed; and the patient is positioned relative to the therapy device by way of the reference means.

As best understood, the Examiner appears to address claim 16 on page 5 of the final Office Action. This portion of the Office Action is reproduced below.

> "Cosman in view of Whitehurst et al. teach all the limitations as described above and further teache determining the position of the implant relative to measuring points (column 3 lines 42-46; column 7 lines 1-6), being connected to the patient or to a couch (fig. 1; fig. 7); and teaches the measuring points are fitted with reference means and patient being moved to the measuring device using reference (fig. 4) and further teaches a three-dimensional tracking system being an optical infrared camera (camera C2). However, Cosman in view of Whitehurst do not teach the patient being situated in a space or region in which there are few interference fields as possible and in which there are as few metallic parts as possible. Conventional Radiotherapy practices teach the aforementioned limitations and precautions, being well-known in the art and official notice of such is taken. It would have been obvious to one of ordinary skill in the art to have modified the method as taught by Cosman in view of Whitehurst and to have further included the step of situating the patient for Radiotherapy in an area with few interference fields and external metallic parts in order to prevent distortion in transmission signals and to provide for accurate detecting means."[23]

Absent from the Examiner's rejection is any discussion "after electromagnetic measuring, the patient is moved to a therapy device in such a way that the spatial relationship between the patient and the measuring points is not changed", or "the patient is positioned relative to the therapy device by way of the reference means". Thus, the Examiner has not established a *prima facie* case of obviousness for claim 16.

For at least the above reasons, reversal of the rejection of claim 16 is respectfully requested.

[23] Page 5 of the final Office Action

Claim 17

Claim 17 depends from claim 16 and thus the above comments with respect to claim 16 are also applicable to claim 17. Claim 17 further recites the independent, three-dimensional tracking system is an optical infrared tracking system. The Examiner does not appear to specifically address the features of claim 17 in the final Office Action. Thus, the Examiner has not established a *prima facie* case of obviousness for claim 17.

For at least the above reasons, reversal of the rejection of claim 17 is respectfully requested.

Claim 18

Claim 18 depends from claim 3 and thus the above comments with respect to claim 3 are also applicable to claim 18. Claim 18 further recites at least one of the steps is performed in a space adjacent to a treatment position; and a tracking system additionally tracks the movement and position of external infrared markings, wherein the position and movement of the implant is referenced with respect to the position and movement of the external markings, and wherein positioning, gating and/or beam tracking are based only on tracking the external markings. The Examiner's comments in support of the rejection are reproduced below.

> "Cosman further teaches at least one of the steps is performed in a space adjacent to a treatment position (fig. 7); and a wherein a tracking system additionally tracks the movement and position of external infrared markings (arrows 26), wherein the position and movement of the implant is referenced with respect to the position and movement of the external markings, and wherein positioning, are based only on tracking the external markings (abstract; column 2 lines 21-37)."[24]

[24] Pages 4-5 of the final Office Action

The cited portions of *Cosman* are reproduced below.

> "A system for positioning and repositioning of a portion of a patient's body with respect to a treatment or imaging machine includes multiple cameras to view the body and the machine. Index markers, either light-emitting, passive, geometric shapes, or natural landmarks, are identified and located by the cameras in 3D space. In one embodiment, such reference or index markers are in a determinable relationship to analogous markers used during previous image scanning of the patient. Anatomical targets determined from image scanning can be located relative to reference positions associated with the treatment or diagnostic machine. Several forms of camera, index markers, methods and systems accommodate different clinical uses. X-ray imaging of the patient further refines anatomical target positioning relative to the treatment or diagnostic imaging reference point. Movements of the patient based on comparative analysis of imaging determined anatomical targets relative to reference points on treatment or diagnostic apparatus are controlled by the system and process of the invention.
>
> Generally, in accordance herewith, an optical camera apparatus functions in cooperation with a LINAC machine and a computer to enable treatment of a patient with a beam that is positioned and maintained on a specific target in a patient's body. In an embodiment, the camera system is located in a known position with regard to the LINAC machine and to detect index markers at specific locations on a patient's body. The markers employed during image scanning processes correlate to reference points for the scan data. Thus, by correlation, anatomical targets in the body, identified in the image scan data are effectively positioned with respect to the treatment beam from the LINAC machine identified by camera data. Essentially, data accumulation, transformation and processing operations serve to correlate scan data with camera data and thereby enable the desired positional relationships for patient treatment as well as providing an effective graphics display."

The Examiner's reliance on the passage above is misplaced. The passages are devoid of any disclosure of "movement of the implant is referenced with respect to the position and movement of the external markings" or "wherein positioning, gating and/or beam tracking are based only on tracking the external markings." Thus, the Examiner has not established a prima facie case of obviousness for claim 18.

For at least the above reasons, reversal of the rejection of claim 18 is respectfully requested.

Claim 19

Claim 19 is the only other independent claim in issue and the Examiner relies on the same arguments for claims 1 and 19. Claim 19 is directed to recording diagnostic, two dimensional or three dimensional image data sets in accordance with breathing of a patient. The method includes introducing at least one implant into a patient in the vicinity of the target volume; inductively stimulating the at least one implant; detecting emission from the at least one inductively stimulated implant; determining a position of the at least one implant based on the detected emission; and recording image data based on the position of the at least one implant.

Like the method of claim 1, the method of claim 19 is directed to the use of an implant that may be inductively stimulated to produce an emission. The emission is used in determining the position of the implant. Unlike claim 1, the ***position of the implant is also used to control image recording in accordance with a patient's breathing***. The Examiner does not appear to specifically address this feature of claim 19 in the final Office Action. Thus, in addition to the reasons discussed above with respect to claim 1, claim 19 is further distinguishable over *Cosman* and *Whitehurst* the above reasons.

For at least the above reasons, reversal of the rejection of claim 19 is respectfully requested.

Claim 20

Claim 20 depends from claim 19 and further recites at the imaging system, generating a dynamic electromagnetic field in the vicinity of but outside of the patient, wherein the at least one implant inductively absorbs energy via the electromagnetic field and the at least one implant at least partially re emits the absorbed energy in the form of an electromagnetic signal; detecting the electromagnetic signal outside the patient; determining the position and/or orientation of the at least one implant relative to measuring points at which the electromagnetic signal is detected, the position of said measuring points relative to the imaging system being known; and based on knowledge of the position of the at least one introduced implant, causing the imaging system to record data only when the position of the implant is within a tolerance range within the patient.

The above discussion relating to claim 19, as well as the discussion relating to claims 3 and 16, are applicable to claim 20. In addition, the Examiner does not appear to specifically address claim 20, or, if claim 20 has been addressed, *Cosman* and/or *Whitehurst* have not been shown to disclose recording "data only when the position of the implant is within a tolerance range within the patient." Thus, the Examiner has not established a *prima facie* case of obviousness for claim 20.

For at least the above reasons, reversal of the rejection of claim 20 is respectfully requested.

VIII. Conclusion

In view of the foregoing, it is respectfully submitted that the claims are patentable over the applied art and that the rejections advance by the Examiner should be reversed.

Respectfully submitted,

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Claims Appendix

1. A method for detecting a target volume in radiotherapy or radiosurgery, said method comprising:

positionally referencing at least one implant in the vicinity of the target volume;

inductively stimulating the at least one implant;

detecting emission from the at least one inductively stimulated implant;

determining a position of the at least one implant based on the detected emission; and

determining the current position of the target volume based on the determined position of the at least one implant.

2. The method as set forth in claim 1, further comprising:

introducing the at least one implant into a patient in the vicinity of the target volume;

detecting the position of the at least one introduced implant using an imaging system before a radiation treatment;

referencing the at least one introduced implant relative to inner organs or other body structures.

3. The method as set forth in claim 2, further comprising:

after detecting the position of the at least one introduced implant, moving the patient to a therapy device;

at the therapy device, generating a dynamic electromagnetic field from a location in the vicinity of but outside the patient, wherein the at least one implant inductively absorbs energy via the electromagnetic field and the at least one implant at least partially re-emits the absorbed energy in the form of a second electromagnetic signal;

detecting the second electromagnetic signal from a location outside the patient; and

determining the position of the at least one implant relative to measuring points at which the second electromagnetic signal is detected, the position of said measuring points relative to the therapy device being known.

4. The method as set forth in claim 3, further comprising:

determining the current position of the target volume based on the determined position of the at least one implant and knowledge of the position of the patient's inner organs relative to the at least one implant.

5. The method as set forth in claim 4, further comprising:

shifting the patient such that the target volume can be captured by a therapy beam from the therapy device.

6. The method as set forth in claim 4, further comprising:

adjusting a therapy beam from the therapy device to the current position of the target volume.

7. The method as set forth in claim 4, further comprising:

continuously detecting the position of the at least one implant; and

based on the continuously detected position, determining a shift in the position of the target volume caused by breathing.

8. The method as set forth in claim 4, further comprising:

based on the current position of the at least one implant, activating the therapy device only when the position of the target volume is within a predetermined range about a current target point of the therapy device.

9. The method as set forth in claim 8, wherein knowledge of the current position of the target volume within the patient is used to adjust the therapy device such that the target point of the therapy device follows the shift of the target volume.

10. The method as set forth in claim 3, wherein the measuring points are situated on a rotating portion of a linear accelerator.

11. The method as set forth in claim 3, wherein the measuring points are integrated into a treatment couch of the therapy device.

12. The method as set forth in claim 3, wherein one or more measuring points are attached to a solid, mobile structure which position relative to the therapy device is tracked three-dimensionally by means of a real-time tracking system.

13. The method as set forth in claim 2, wherein the at least one implant includes one or more coils.

14. The method as set forth in claim 13, wherein the at least one implant includes a number of coils whose axes are not parallel to each other.

15. The method as set forth in claim 13, wherein the coils in the at least one implant are connected to different oscillating circuits having different resonance frequencies.

16. The method as set forth in claim 1, wherein:

while the at least one implant is tracked, a patient is situated in a space or region of a space in which there are as few interference fields as possible and in which there are as few metallic parts as possible;

the position of the at least one implant relative to measuring points is determined;

the measuring points are fixedly connected to the patient or to a couch on which the patient is lying;

the measuring points are fitted with a reference means which allows the position of the measuring points to be determined using an independent, three-dimensional tracking system;

after electromagnetic measuring, the patient is moved to a therapy device in such a way that the spatial relationship between the patient and the measuring points is not changed; and

the patient is positioned relative to the therapy device by way of the reference means.

17. The method as set forth in claim 16, wherein the independent, three-dimensional tracking system is an optical infrared camera system.

18. The method as set forth in claim 3, wherein:

at least one of the steps is performed in a space adjacent to a treatment position; and

a tracking system additionally tracks the movement and position of external infrared markings, wherein the position and movement of the implant is referenced with respect to the position and movement of the external markings, and wherein positioning, gating and/or beam tracking are based only on tracking the external markings.

19. A method for recording diagnostic, two-dimensional or three-dimensional image data sets in accordance with breathing, said method comprising:

introducing at least one implant into a patient in the vicinity of the target volume;

inductively stimulating the at least one implant;

detecting emission from the at least one inductively stimulated implant;

determining a position of the at least one implant based on the detected emission; and

recording image data based on the position of the at least one implant.

20. The method as set forth in claim 19, further comprising:

at an imaging system, generating a dynamic electromagnetic field from a location in the vicinity of but outside of the patient, wherein the at least one implant inductively absorbs energy via the electromagnetic field and the at least one implant at least partially re-emits the absorbed energy in the form of an electromagnetic signal;

detecting the electromagnetic signal from a location outside the patient;

determining the position and/or orientation of the at least one implant relative to measuring points at which the electromagnetic signal is detected, the position of said measuring points relative to the imaging system being known; and

based on knowledge of the position of the at least one introduced implant, causing the imaging system to record data only when the position of the implant is within a tolerance range within the patient.

Evidence Appendix

None.

Related Proceedings Appendix

None.